MAR 23 2010

K083842

510(k) Summary

1. Submitter's Name / Contact Person

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2. Identification of the Product

Trade Name:	ROTEM® *delta* Thromboelastometry System
Common Name:	Whole Blood Haemostasis System
Classification Name:	Multipurpose System for In Vitro Coagulation Studies

3. Identification of the Predicate

Thrombelastograph® Coagulation Analyzer (TEG®) – 5000 Series K002177, Product Code JPA, Haemoscope Corp.

4. Description of the Device

The ROTEM® *delta* Thromboelastometry System consists of a four-column instrument (with integrated computer module, computer controlled electronic pipette, software), system reagents (in-TEM®, hep-TEM®, star-TEM®), quality controls (ROTROL N, ROTROL P) and measurement cells (Cup and Pin pro). The blood sample is filled into a cylindrical cup. A pin oscillates permanently while it is immersed in the blood holding cup. The motion of the pin is detected by an optical detection system. Data are processed and analyzed by a computer with special software. If no clotting takes place, the movement of the pin is not obstructed. When a clot forms and attaches itself to the pin and cup surfaces, the movement is obstructed. As the clot becomes firmer, the rotational movement of the pin is reduced. The rotational

movement of the pin is converted into an amplitude with the following definitions applying to the thromboelastogram (TEM): An amplitude of 0 mm means unobstructed rotation, while an amplitude of 100mm can be regarded as infinite firmness and blocking of the pin by the clot. The TEM amplitude is a measure of the clot firmness.

5. Intended Use

The ROTEM® *delta* Thromboelastometry System is designed for in-vitro diagnostic use by professionals in a laboratory environment. The ROTEM® system is intended to be used to provide a qualitative and quantitative indication of the coagulation state of a blood sample. For this purpose the ROTEM® system records the clot firmness changes in a sample of citrated whole blood as the sample clots, retracts and lyses in real time. The analyzer output consists of a qualitative graphical representation (mirrored coagulation curve – clot firmness over time) and several defined numerical parameters describing the curve quantitatively.

The ROTEM® system provides specific blood modifiers (so-called reagents) intended to be used with the system, as additive to the blood sample.

The results of the ROTEM® analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history (anamnesis), the clinical picture and, if necessary, further coagulations tests.

6. Summary of Technological Characteristics of the Product, Compared with the Predicate Device

	ROTEM® *delta*	TEG® 5000
Instrument	Fully integrated Thromboelastometry instrument	Thrombelastography instrument
Measuring Technique	Shear elasticity of a coagulating sample by motion of pin	Shear elasticity of a coagulating sample by motion of cup
Measuring Channels	4	2
Signal Generation	Oscillating pin in stationary cup	Oscillation cup around stationary pin
Signal Transducer	Optical 4 CCD chips	Electrical-mechanical transducer
Temperature Control	30-40 °C	20-40 °C

Sample Volume	300 µl	360 µl
Total Reaction Volume	320-340 µl	360-380 µl
Voltage	110-230 V, 50-60 Hz	120 V, 60 Hz and 220 V, 50 Hz model available
Environment	Stable and level surface. Operating temperature: 15-30 °C. Storage temperature 0-50 °C, rel. humidity 20-85%.	Vibration free position, no solar radiation. Operating temperature: 10-35 °C. Storage temperature -30-50 °C, rel. humidity 20-80%
Operating Position	Level to 5° inclination	Level ad justed by leveling feet and level
Operable to Height above Sea Level	2000 m (6560 ft)	3048 m (10000 ft)
Initial Warm Up Time	5-15 min (depending on room temperature)	5 min
Pipetting	Electronic pipette (20-320 µl)	Manual pipettes (10, 20, 360, 1000 µl)
Reagents / Accessories:		
Intrinsic Contact Activation Reagent	in-TEM® (ellagic acid)	Kaolin
Heparinase I Reagent (for heparin neutralization)	hep-TEM® (heparinase I, $CaCl_2$)	Cup (single use) coated with heparinase I or Heparinase I reagent
Calcium Chloride Reagent (for recalcification)	star-TEM® ($CaCl_2$)	$CaCl_2$ reagent
Quality Control Material (level I control)	ROTROL N	TEG® coagulation control – level I
Quality Control Material (level II control)	ROTROL P	TEG® coagulation control – level II
Cups & Pins	Cup & Pin pro (Acrylic plastic disposables)	Cups & Pins (Acrylic plastic disposables)

7. Executive Summary of the Study Report

In this study, the performance characteristics of the ROTEM® *delta* Whole Blood Haemostasis System (ROTEM®) were investigated and three assays were compared to the predicate device TEG® 5000 (TEG®) in support of a 510(k) submission for ROTEM®.
The three ROTEM® tests NATEM, INTEM and HEPTEM were compared to their predicate tests on TEG®. The NATEM test represents the classical non-activated thrombelastographic method corresponding to the non-activated TEG®. The INTEM is activated by the intrinsic activator reagent ellagic acid corresponding to the intrinsically activated Kaolin test on TEG®. The HEPTEM is activated as the INTEM by ellagic acid and additionally contains heparinase for heparin neutralization corresponding to the Kaolin + Heparinase test of TEG®.
For all three tests, the ROTEM® was shown to have high precision in its primary parameter clot firmness and adequate precision in its secondary coagulation kinetics parameters.
The method comparison with TEG® showed equality of the clot firmness (MCF vs. MA). The kinetic parameters (CT vs. R, CFT vs. K, Alpha Angle vs. Angle) showed a linear correlation between ROTEM® and TEG® ($r>0.8$). As expected, slope of the correlation between the two systems was not equal to one and intercepts were not equal to zero in the kinetic parameters as the respective tests use different activation reagents and each test has its own distinct reference ranges. Heparin sensitivities of the respective intrinsic ROTEM® and TEG® tests also differed. ROTEM® was more sensitive for higher heparin concentrations than TEG® and allowed for an analysis of heparin concentrations normally seen during cardiovascular surgery; while TEG® was unable to demonstrate any coagulation in these cases.
Reference ranges for the ROTEM® tests NATEM and INTEM were estimated using CSLI protocols on three clinical US reference sample groups. The reference ranges determined showed no significant center-to-center deviations and were in accordance with the reference ranges determined in earlier studies on European reference sample groups.
Three interfering substances widely used in coagulation management, the antifibrinolytic drugs aprotinin, tranexamic acid and epsilon-amino caproic acid (EACA) were investigated. Dose-response curves were investigated for heparin, for dilution and for urokinase on the INTEM model in order to verify the diagnostic principles of thrombelastographic methods on ROTEM®.

In summary, ROTEM® is a precise Whole Blood Haemostasis System with the typical performance characteristics of a thrombelastographic method (aprotinin interference on the contact activated and intrinsically activated tests, heparin sensitivity of the intrinsic test and sensitivity to dilution and lysis induced by urokinase in-vitro). Its reference ranges are reproducible from center to center. The method comparison with TEG® shows equality of the primary parameter clot firmness and a linear regression and good correlation in the secondary kinetic parameters. In comparison to the TEG® the ROTEM® is optimized for a rapid diagnosis (employing stronger activation for shorter activation and test times) accompanied by a shift of the detection range of heparin in the intrinsically activated test.
In aggregate the data presented in this report demonstrate that the ROTEM® system and the three assays described are substantially equivalent to the predicate TEG® System and corresponding assays.

8. Conclusion (Statement of Equivalence)

The data and information provided in this submission support a substantial equivalence determination, and, therefore, clearance of the 510(k) premarket notification for the ROTEM® *delta* Thromboelastometry System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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MAR 2 3 2010

Re: k083842
Trade/Device Name: ROTEM® *delta* Thromboelastometry System:
in-TEM® Assay
hep-TEM® Assay
NATEM® Assay
Star-TEM®
ROTEM® *delta* instrument
ROTROL N
ROTROL P
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for *in vitro* coagulation studies
Regulatory Class: Class II
Product Code: JPA, GGN
Dated: July 27, 2009
Received: July 29, 2009

Dear Dr. Friemert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21,

Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083842

Device Name:
ROTEM® *delta* Thromboelastometry System

Indications for Use
The ROTEM® *delta* is a non-invasive diagnostic instrument designed to monitor and analyze the coagulation state of a blood sample in order to assist in the assessment of patient clinical hemostasis conditions. The indication for ROTEM® *delta* use is with adult patients where an evaluation of their blood coagulation properties is desired.
Coagulation evaluations with the ROTEM® *delta* are commonly used to assess clinical conditions in organ transplantation, cardiovascular surgery, cardiology procedures and trauma to assess post-operative hemorrhage and / or thrombosis.

Prescription Use) ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K083842

Indications for Use

510(k) Number (if known): K083842

Device Name:
ROTROL N

Indications for Use

ROTROL N is a quality control material for monitoring accuracy and precision of tests carried out on the ROTEM® *delta* Thromboelastometry System.

Prescription Use) ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Device Evaluation and Safety

510(k) K083842

Indications for Use

510(k) Number (if known): K083842

Device Name:
ROTROL P

Indications for Use

ROTROL P is a quality control material for monitoring accuracy and precision of tests carried out on the ROTEM® *delta* Thromboelastometry System.

Prescription Use) ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Device Evaluation and Safety

510(k) K083842

Indications for Use

510(k) Number: K083842

Device Name:
in-TEM® Assay

Indications for Use

The in-TEM® assay is a semi-quantitative *in vitro* diagnostic assay used on the ROTEM® *delta* Thromboelastometry System to monitor the coagulation process via the intrinsic pathway in citrated whole blood specimens. Clotting characteristics are described by the functional parameters Clotting Time (CT), Speed of Clot Formation (CFT and alpha angle), Clot Firmness (A20/MCF) and Clot Lysis (LOT, ML, LI(x)).

The indication for ROTEM® *delta* use is with adult patients where an evaluation of their blood coagulation properties is desired. Coagulation evaluations with the ROTEM® *delta* are commonly used to assess clinical conditions in organ transplantation, cardiovascular surgery, cardiology procedures and trauma to assess post-operative hemorrhage and / or thrombosis.

Prescription Use) ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Device Evaluation and Safety

510(k) K083842

Indications for Use

510(k) Number: K083842

Device Name:
hep-TEM® Assay

Indications for Use

The hep-TEM® assay is a semi-quantitative *in vitro* diagnostic assay used on the ROTEM® *delta* Thromboelastometry System to monitor the coagulation process, via the intrinsic pathway in the presence of unfractionated heparin, in citrated whole blood specimens. The hep-TEM® reagent is used to inactivate heparin in patients receiving unfractionated heparin. Clotting characteristics are described by the functional parameters Clotting Time (CT), Speed of Clot Formation (CFT and alpha angle), Clot Firmness (A20/MCF) and Clot Lysis (LOT, ML, LI(x)).

The indication for ROTEM® *delta* use is with adult patients where an evaluation of their blood coagulation properties is desired. Coagulation evaluations with the ROTEM® *delta* are commonly used to assess clinical conditions in organ transplantation, cardiovascular surgery, cardiology procedures and trauma to assess post-operative hemorrhage and / or thrombosis.

Prescription Use) ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510(k) K083842

Indications for Use

510(k) Number: K083842

Device Name:
NATEM Assay

Indications for Use

The NATEM assay is a semi-quantitative *in vitro* diagnostic assay used on the ROTEM® *delta* Thromboelastometry System to monitor the coagulation process, contact-activated by the surface of the measurement cell, in citrated whole blood specimens. Clotting characteristics are described by the functional parameters Clotting Time (CT), Speed of Clot Formation (CFT and alpha angle), Clot Firmness (A20/MCF) and Clot Lysis (LOT, ML, LI(x)).

The indication for ROTEM® *delta* use is with adult patients where an evaluation of their blood coagulation properties is desired. Coagulation evaluations with the ROTEM® *delta* are commonly used to assess clinical conditions in organ transplantation, cardiovascular surgery, cardiology procedures and trauma to assess post-operative hemorrhage and / or thrombosis.

Prescription Use) ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Device Evaluation and Safety

510(k) K083842

Indications for Use

510(k) Number: K083842

Device Name:
Star-TEM® Reagent

Indications for Use

The star-TEM® Reagent is intended for use as a recalcification reagent in the NATEM and INTEM assays on the ROTEM® delta Thromboelastometry System.

The indication for ROTEM® *delta* use is with adult patients where an evaluation of their blood coagulation properties is desired. Coagulation evaluations with the ROTEM® *delta* are commonly used to assess clinical conditions in organ transplantation, cardiovascular surgery, cardiology procedures and trauma to assess post-operative hemorrhage and / or thrombosis.

Prescription Use) ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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